



March 11, 2019

Subcommittee on Economic and Consumer Policy,
Committee on Oversight and Reform
U.S. House of Representatives
Washington, D.C. 20515

Dear Members of the Subcommittee:

Tomorrow's hearing on public health risks in consumer products raises significant and important public policy issues that deserve to be examined in a thorough, rigorous, and impartial manner. Johnson & Johnson has dedicated significant resources to providing the public with open and transparent information regarding Johnson's Baby Powder, cosmetic talc, and talc safety, including through a dedicated website, Facts About Talc, where the company has posted more than 1,500 documents of studies, letters, and other materials covering decades of information about cosmetic talc. This letter summarizes key information about talc safety and seeks to correct erroneous information that has been recently repeated by the media.

Johnson's Baby Powder Is Safe

The science is clear. Decades of independent scientific testing has confirmed that Johnson & Johnson's cosmetic talc and Johnson's Baby Powder are safe, are not contaminated with asbestos, and do not cause cancer. The FDA, global regulators, and leading independent labs have collectively tested Johnson & Johnson's cosmetic talc for decades and repeatedly affirmed that it does not contain asbestos.

Indeed, just last week, the FDA restated its findings from an earlier study in which it tested both Johnson's Baby Powder and the cosmetic talc supplied to Johnson & Johnson, in addition to 34 other cosmetics products. Using "the most sensitive techniques available," the FDA found that none of the products tested, including Johnson's Baby Powder and the cosmetic talc used in Johnson's Baby Powder, contained asbestos.¹ Numerous global regulators have recently affirmed the safety of Johnson & Johnson's cosmetic talc products.² Likewise, scientists from Harvard, MIT, Princeton, Dartmouth, Mt. Sinai Medical Center, the National Institute for Occupational Safety and Health, and many others have time and again confirmed

¹ Food and Drug Administration, Statement from FDA Commissioner Scott Gottlieb, M.D., and Susan Mayne, Ph.D., Director of the Center for Food Safety and Applied Nutrition (Mar. 5, 2019), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632736.htm> (citing results from FDA's 2009-10 study, which surveyed over 34 products, including Johnson's Baby Powder, and linking to FDA's general webpage on talc, <https://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm293184.htm>).

² See *Government of India Reaffirms the Safety of Johnson & Johnson's Talc* (Feb. 28, 2019), <https://www.factsabouttalc.com/assets/pdfs/news/Feb28-2019.pdf>; JFDA, "Johnson Baby Powder" Is Free from Carcinogens, Jordan News Agency (Dec. 17, 2018) (translation).

EXHIBIT

601.013

that Johnson & Johnson's cosmetic talc products do not contain asbestos.³ Multiple scientific, peer-reviewed studies of tens of thousands of men and women reflect that cosmetic talc does not cause cancer.⁴

Johnson & Johnson has been working cooperatively with regulators on these issues for decades. When media reports first raised issues regarding cosmetic talc in the 1970s, Johnson & Johnson worked swiftly with the FDA and leading scientists to demonstrate that its baby powder was safe.⁵ After performing its own testing, the FDA concluded, in 1976, that Johnson & Johnson's products were not contaminated with asbestos.⁶ Unfortunately, plaintiffs' lawyers and others have sought to misuse or mischaracterize historical documents in an attempt to rewrite history, but the facts and documentary record are clear.

Johnson & Johnson's Decades of Testing of Cosmetic Talc

In 1976, the cosmetics industry established a testing standard to ensure the safety of cosmetic talc, called the CTFA J4-1 specification, which was subsequently acknowledged by FDA as well. The J4-1 standard requires the use of x-ray diffraction (XRD), and, where necessary for additional screening, polarized light microscopy (PLM). Johnson & Johnson has used XRD and PLM for decades, and indeed, currently uses both methods in accordance with the United States Pharmacopeia recommendations for ensuring that pharmaceutical-grade talc is asbestos free. In addition to using XRD and PLM in accordance with the United States Pharmacopeia and J4-1 methods, Johnson & Johnson uses transmission electron microscopy (TEM) to assess its cosmetic talc.⁷ Johnson & Johnson tests the sites where its cosmetic talc is mined, the raw ore taken out of the earth, and the milled powder before it is bottled.⁸

In addition to Johnson & Johnson's own testing, independent experts and authorities have analyzed its sources and products. Government agencies such as the FDA and the National Institute for Occupational Safety and Health, leading labs including the McCrone Group, and scientists from world-class universities like Harvard and MIT have all confirmed that Johnson & Johnson's cosmetic talc products are safe and do not contain asbestos.

³ See, e.g., Boundy et al., Occupational Exposures to Non-Asbestiform Talc in Vermont *in* DUSTS AND DISEASE 365 (R. Lemen & J.M. Dement eds., 1979); Martin Buerger, REPORT TO DR. A. L. GOUDIE, (1972); R.C. Reynolds, X-RAY AND OPTICAL EXAMINATION OF TALC PRODUCTS (1971); Press Release, Mt. Sinai Medical Center, Statement by Dr. Thomas Chalmers (Mar. 23, 1976).

⁴ See, e.g., Rubino et al., *Mortality Study of Talc Miners and Millers*, 18 J. OCCUP. MED. 186 (1976); Pira et al., *Updated Mortality Study of a Cohort of Asbestos Textile Workers*, CANCER MEDICINE (2017); Gertig et al., *Prospective Study of Talc Use and Ovarian Cancer*, 92 J. NATL. CANCER INST. 249 (2000); Gates et al., *Risk Factors for Epithelial Ovarian Cancer by Histologic Subtype*, 171 AM. J. EPIDEMIOLOGY 45 (2010).

⁵ See, e.g., Letter from W. Nashed of Johnson & Johnson to FDA (Oct. 17, 1972).

⁶ See Memorandum from Ronald Yates, FDA, to Heinz Eiermann, FDA (Jan. 7, 1976).

⁷ See JOHNSON & JOHNSON RAW MATERIAL SPECIFICATION (2014).

⁸ See Fred Pooley, REPORT ON THE EXAMINATION OF ROCK SAMPLES FROM THE VERMONT TALC MINE (1972); Fred Pooley, AN EXAMINATION OF MINE SAMPLES AND RELEVANT POWDERS (1972); Memo from A. Frank to G. Lee on Audit Testing of Windsor 66 Talc for Asbestos (June 28, 1977).

FDA's Past Conclusions on Talc's Safety

Since the 1970s, the FDA has repeatedly examined talc safety and investigated allegations regarding public health and cosmetic talc. On each occasion, the FDA has concluded that Johnson & Johnson's products do not contain asbestos and do not cause cancer. In 1986, the FDA responded to a citizen petition and determined that cosmetic talc did not warrant a warning about the presence of asbestos. Importantly, the FDA determined that certain of the early analytical results from the early 1970s and before—many of the same materials cited by plaintiffs' lawyers and news reports today to suggest the presence of asbestos in talc—were of “questionable reliability” due to the lack of agreement around which methods were well-suited for analyzing cosmetic talc.⁹

In 2010, the FDA released the results of its own testing of talcum powder products and sources. The agency found that Johnson & Johnson's products and source materials did not contain asbestos.¹⁰ In 2014, after years of additional scientific research being published, the FDA concluded that cosmetic talc did not warrant warnings about cancer. The FDA reviewed decades of scientific investigations of possible links between ovarian cancer and talc and concluded that there was “no conclusive evidence to support” a causal connection between talc and ovarian cancer.¹¹

Cosmetic Talc Does Not Cause Cancer

Numerous epidemiological studies over several decades have examined whether differences in exposure to talc are associated with differences in disease occurrence. For example, studies have followed thousands of miners and millers working in talc production in Italy, Vermont, France, and elsewhere.¹² Because these personnel work in talc producing occupations, the miners and millers are exposed to talc at massively larger quantities than consumers. Yet these studies have not identified a single person with mesothelioma, the cancer associated with asbestos. These studies include workers dating to the 1920s and have been updated as recently as 2017, continuing to show no instances of mesothelioma.¹³

Additionally, several studies have examined whether there is a causal link between the use of cosmetic talc and ovarian cancer. Three large, prospective cohort studies of tens of thousands of women did not find any such link. In 2000 and 2010, the Nurses' Health Study, which considered more than 40,000 nurses who reported use of cosmetic talc as of 1982,

⁹ Letter from H.W. Swanson, FDA, to Phillippe Douillet, Docket No. 83P-0404 (July 11, 1986).

¹⁰ *Cosmetics Ingredients: Talc*, FDA (last updated Aug. 21, 2018).

¹¹ Letter from Steven Musser, FDA, to Dr. Samuel Epstein, Cancer Prevention Coalition, Docket Nos. 94P-0420, FDA-2008-0309-0001/CP (Apr. 1, 2014). FDA also observed that there is still no “cogent biological mechanism by which talc might lead to ovarian cancer.” *Id.*

¹² See, e.g., Rubino et al., *Mortality Study of Talc Miners and Millers*, 18 J. OCCUP. MED. 186 (1976), Pira et al., *Updated Mortality Study of a Cohort of Asbestos Textile Workers*, CANCER MEDICINE (2017), Selevan et al., *Mortality Patterns Among Miners and Millers of Non-Asbestiform Talc: Preliminary Report*, 2 J. ENV. PATH. & TOXIC. 273 (1979), Wild et al., *A Cohort Mortality and Nested Case-Control Study of French and Austrian Talc Workers*, 59 J. OCCUP. ENVIRON. MED. 98 (2002).

¹³ Pira et al., *Updated Mortality Study of a Cohort of Asbestos Textile Workers*, CANCER MEDICINE (2017).

concluded that the use of cosmetic talc had no overall effect on the occurrence of ovarian cancer.¹⁴ A separate study in 2014, and part of the Women's Health Initiative, considered more than 30,000 perineal users of cosmetic talc and concluded there is no increased risk of ovarian cancer from the use of cosmetic talc.¹⁵ In 2016, a third study, the Sister Study, considered nearly 6,000 women who were talc users and again found no association between cosmetic talc use and ovarian cancer.¹⁶

Litigation Results

Although Johnson & Johnson has both won and lost some jury trials, no jury verdict against Johnson & Johnson has been upheld on appeal. Johnson & Johnson has received six trial judgments in our favor. There have been nine judgments in favor of plaintiffs; three have been reversed, five are on or nearing appeal, and one reached a conclusion of zero damages. Additionally, dozens of lawsuits against Johnson & Johnson have been dismissed.

Commitment to Public Health and Safety

Johnson & Johnson recognizes that we have an obligation to our customers to ensure that our products are safe. And Johnson & Johnson expresses its deepest sympathies to the patients and families struggling with cancer. For that reason, Johnson & Johnson has gone above and beyond the industry standard when ensuring the safety of our cosmetic talc products. We support efforts to examine the science and evidence concerning talc safety in a thorough, rigorous, and impartial manner.

Nothing is more important to us than the safety of consumers and maintaining their trust in our products. We have long supported legislation to modernize the FDA's regulatory authority over cosmetics and personal care products, and believe this reform is essential to enabling the agency to increase its ability to protect the public. We are committed to continuing to work with Congress and the FDA to advance meaningful change.

We encourage the Subcommittee members, your staff, and the interested public to review the information and documents posted on Facts About Talc. Johnson & Johnson is committed to an open and transparent discussion about talc safety, and we thank the Subcommittee for its interest in this important matter.

Sincerely,
Johnson & Johnson

¹⁴ Gertig et al., *Prospective Study of Talc Use and Ovarian Cancer*, 92 J. NATL. CANCER INST. 249 (2000); Gates et al., *Risk Factors for Epithelial Ovarian Cancer by Histologic Subtype*, 171 AM. J. EPIDEMIOL. 45 (2010).

¹⁵ Houghton et al., *Perineal Powder Use and Risk of Ovarian Cancer*, J. NATL. CANCER INST., September 2014.

¹⁶ Gonzalez et al., *Douching, Talc Use, and Risk of Ovarian Cancer*, 27 EPIDEMIOLOGY 797 (2016). Notably, this group of women was already at a significantly higher risk than the normal population for developing ovarian cancer.